Dear Official Correspondent:

Enclosed is form FDA 2891a, Annual Registration of Device Establishment. The form has changed **substantially**. Also, a report showing any medical device listings your establishment has on file with the Food and Drug Administration (FDA) has been included.

Please note that - for this mailing only - the boxes that indicate your current establishment type(s) in Section 2 of the form are not checked. If you have no changes to report for your establishment type(s), please leave this section blank. If you are unsure about your current establishment type(s) please review your data in our web based database which can be found by going to the Registration and Listing Internet homepage at http://www.fda.gov/cdrh/reglistpage.html. Do not check off any operations unless you are adding new types or deleting establishment types you have previously reported. Future mailings of the form will include this information.

Please do the following:

- Complete, sign and return the **original** form, FDA 2891a, within 30 days of receipt. By returning the form, you will be renewing your establishment registration for the entire year of 2006. **Failure to return the form will result in the establishment not having a valid FDA medical device establishment registration**.
- Review your enclosed device listing records and report any changes on form(s) FDA 2892, Device Listing. FDA cannot make any updates, additions or deletions to your listing records from any source other than form FDA 2892. Please do not return the enclosed device listing report.

Return all forms to:

Food and Drug Administration
Center for Devices and Radiological Health
HFZ-308
9200 Corporate Blvd.
Rockville, MD 20850-4015

As there is no detachable "coupon" on this form as there had been on previous versions, you must make your own photocopy if you wish to retain a copy. FDA will send you a confirmation letter or email upon receipt of your updated FDA 2891a form. You can verify that FDA has properly updated your registration information by reviewing your data in our web based database. Our web-based database is updated only once per month, on or about the 6th of each month.

Registration and Listing Program Changes and Issues:

- Please review your email address as shown on the enclosed form FDA 2891a carefully, as FDA will begin sending your annual registration and other communications by email in the near future. If you have not yet provided your email address, please be sure to do so in Section 5 of this annual registration form.
- The Registration and Listing program is now a part of the Regulatory Policy and Systems Branch of the Division of Risk Management Operations. Please send all correspondence to the address listed above.

Policy Issues:

- **Limitations on Exemptions:** If you believe your medical device is classified as exempt from the premarket notification (510(k)) requirements of the Federal Food, Drug and Cosmetic Act, please be aware that all device types classified as exempt from the 510(k) requirements are subject to the limitations on exemptions. Limitations of device exemptions are found in the device classification chapters in 21 CFR xxx.9, where xxx refers to Parts 862-892 (e.g., 862.9, 889.9, etc.). Please be aware that it is your responsibility to ensure that you meet the exemption criteria and your device does not exceed the limitations of exemption. If your device exceeds the limitations to exemption, you must submit a 510(k) and receive a letter from FDA stating that your device may be commercially distributed in the U.S. prior to marketing your device.

- **Misbranding by Reference to Establishment Registration or Registration Number in Labeling or on Internet Sites**: The Code of Federal Regulations, Chapter 21, Section 807.39, states that "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." If your product labeling or Internet site list your establishment registration number or makes reference to your establishment being registered and approved by the FDA, then these references must be removed.

If you have any policy related questions, please contact the Registration and Listing program staff at rlprogram@cdrh.fda.gov or by calling call (240) 276-0110. To inquire about the status of a submission or to request forms or obtain help completing forms, please send an e-mail message to reglist@cdrh.fda.gov or call (240) 276-0111.

Sincerely yours,

David Gartner
Regulatory Policy and Systems Branch
Office of Compliance
Center for Devices and Radiological Health